PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	The impact of self-efficacy and health literacy on outcome after bariatric surgery in Sweden: a protocol for a prospective, longitudinal mixed methods study
AUTHORS	Jaensson, Maria; Dahlberg, Karuna; Nilsson, Ulrica; Stenberg, Erik

VERSION 1 - REVIEW

REVIEWER	Karen D. Groller, PhD, RN-BC, CMSRN Moravian College, United States
REVIEW RETURNED	07-Nov-2018

GENERAL COMMENTS	The topic under investigation is one of interest to the bariatric community. Determining how health literacy and perceived self-efficacy influence bariatric surgical outcomes may impact long-term management. With that intention, the author(s) of the current manuscript being reviewed failed to provide sufficient information in the discussion section to support the study need and possible implications to practice, education, policy and future research. Additionally, some grammar improvements are needed. Pay heed to run-on sentences, overuse of transitions and sentence organization. Occasional jargon is used rather than words that are more specific and elicit a clear meaning. I hope my feedback will encourage the author(s) to use the following feedback and resubmit their work for potential publication. Page2, line 25-32: Long sentence that loses meaning to the reader and is confusing. Please rework. Remover “There is, therefore, a…” and replace with “The need to investigate…” This phrase deletion provides a clearer message. Page 2, line 40: correct to read “...Sweden; 20 patients will be included…” Add phase or component after “qualitative study” as this demonstrates more of the mixed-methods part of this study (via qualitative phase and quantitative phase) rather than making it seem there were 2 studies being completed. Be sure reference to the study phases are expressed throughout the paper in the same manner. Page 2, line 53: remove “the” before patients. Encourage authors to identify the specific questionnaires’ names being used in the introduction. Page 4, line 43: Regarding “Younger age and female sex…” this finding is not surprising as 70-80% of all patients seeking bariatric surgery are female. I would discuss that thought in your conclusion and how you may sample to ID possible gender differences.

	Page 5, line 29 and line 56: add comma after “To our knowledge,” Page 6, line 25: Is the third hypothesis accurate enough? Is Health literacy the sole factor to have an impact on hospital readmission? Would it read better if you add to the statement, “… and subsequently weight loss” Page 7, lines 17-19: can you identify these sites in the online publication? Is the study still in progress? Page 7, line 41: comment- how is EBMIL different than the excess weight loss (EWL) commonly used post-bariatric surgery? Page 7: Details about about a priori sampling was calculated in the study sample was not fully expressed. Page 7, line 52: First sentence is not structurally sound. Please rephrase. Consider the following, “During their preoperative consultation the surgeons will verbally provide information about the study.” Page 8, lines 42-47: Confusing sentence “ The GSE has been ….” Unclear what versions were all tested. Page 9, line 13-14: Was tool tested on same population? What were the Psychometric testing results? Page 9, lines 16-29: The three factors discussed here—Functional, communicative and critical literacy—are these measured with the short form or original tool or both? Please clarify. Page 9, lines 36-41: odd phrasing. Rework sentence. Page 9, lines 44-49: OK, what psychometric testing will be achieved in your study. Reference to Table 2 is needed. Also consider prioritizing the order of the psychometric evaluation plan in Table 2 (on page 13). Page 10, line 3: RAND needs to be spelled out and then identified by abbreviation. Page 10, lines 20-31: In the section called Obesity-related problem scale more information is needed. Provide more information on who and how this tool was developed and tested. Is this test appropriate for use in a surgical population? What is the intent of using this tool in your study—will it help measure self-efficiacy? Page 10, lines 44-51: Demographics being collected should be identified in more detail. Is there a demographics form that will be used? Is this information extracted from SOReg? If so, please reference Table 1. Page 11, lines 3-4: sentence as written is oddly worded. Rephrase, “Twenty persons who participated in the main study will be included in a qualitative phase using an inductive approach.” Page 11, line 8: remove “the” that preceeds surgery. Also identify “surgery” as bariatric surgery here and throughout your manuscript.

	Page 11, line 13: Mention of a semi-structured interview guide is given. Can this be included as a Figure or Table in your manuscript? Page 11, line 15: Delete “could you” and start sentence with Describe. Page 11, line 17: remove “the” before surgery. Change to bariatric surgery. Page 11, Table 1: Some areas on this table can be combined…For example, BMI and weight variables can be inclusive of all time periods. It is redundant to have “weight at surgery and weight” listed. Page 12, line 39: Delete “to analyze” and start sentence with Demographics. Fix grammar within this sentence to improve reading fluidity. Page 12, lines 42-onward: It would be nice to see the expected statistical test connected to the intended study instrument/tool. For example, GSE will potentially be analyzed using…. Page 13, line 9: Start sentence with Psychometric analysis will be… (Beware excess use of “the”) Page 13, line 49: Interviews will be recorded with what device? Who will be conducting the interviews? Page 14, line 22: Ethics perspective is quite short and not comprehensive of patient protection. Expand to include information that will demonstrate privacy, confidentiality and mechanism to seek help if harmed. Page 14, lines 26-28: Delete first sentence “The study will follow….” Page 14, line31: delete “received” and insert “will” General comments: RE recruitment: when does inclusion criteria check occur? RE qualitative phase procedure: how are final themes extracted from the data checked for creditability? Consider sharing Lincoln and Guba’s validity checks throughout the process. RE GSE instruments: specify version being used and actual or real psychometric properties. Throughout your manuscript pay particular attention to sentence structure and grammar. Regarding ethical concerns. Please expand discussion to provide information on how patient identify will be maintained through copies of data (surveys) and interviews. Who will have access? Where will information be kept when not used by researcher or research team? Page 14, line 40: rephrase to, “This open-access article is distributed…”

	Page 15, line 20: This statement “Nor have research questions such as ours been reported before” Is a sentence fragment— please fix. Page 15, line 37-49: rework to read as follows, “If patients can strengthen their self-efficiacy, they may feel empowered to handle their situation. Also if information provided is appropriate according to their lebel of health literacy,” Page 15, line 42-44: “able to handle” and “to some extent be avoided” is jargon. Please rework.

REVIEWER	Richard Welbourn Dept Upper GI & Bariatric Surgery Musgrove Park Hospital Taunton TA1 5DA UK
REVIEW RETURNED	21-Nov-2018

GENERAL COMMENTS	This is a protocol for a study already with ethical approval on general self-efficacy and health literacy in patients age 18 or over in Sweden between 2 bariatric centres. Major points 1 I am not an expert is power calculation but I would ask the authors to double check the expected weight loss figures. The high % Excess BMI Loss expected presumably relates to the relatively low initial BMI of patients operated in Sweden and is the 1 or 2 year weight expectation. Have the authors taken into account expected weight regain after this time e.g. at 3-4 years after surgery and how would this affect sample size and generalisability of the results? Have the authors taken into account possible poorer weight loss in males and diabetics? 2 The study should gather the information on patients entering the study vs all those approached to ensure data are representative of the whole population. Minor points 1 The choice of Clavien-Dindo of 3b and above should be explained, and an explanation of what Clavien-Dindo is as well should be included if the authors think appropriate. Will they include diagnostic laparoscopy? 2 Which is the baseline weight? That on entry to the weight loss programme or that on the day of surgery? The authors should consider both if there is a preoperative weight loss programme in place. 3 Please explain why it was chosen not to involve patients in study design.

REVIEWER	Chun-Che Huang Taichung Veterans General Hospital / Taiwan
REVIEW RETURNED	09-Dec-2018

GENERAL COMMENTS	The manuscript by Dr. Jaensson and coworkers are going to use a prospective, longitudinal mixed-method study design from two bariatric centers to investigate how a person's self-efficacy and health literacy skills affect recovery and health-related quality of life after surgery in Sweden. This study is an interesting idea that potentially could, but there are several questions need to be made clear or revised. 1. In the Introduction section, (1) In page 5 line 7, '……, depending on fluctuations in one's own personal belief in personal efficacy.' This sentence made me confused. Could the authors please explain a bit? 2. In the Methods and Analysis section, (1) The authors must remember that participants have the right to refuse or withdraw consent at any time for any reason. Please explain how to adapt to the circumstances and state in the text. (2) Do participants who reported low self-efficacy will be judged by a clinician or psychological expert? Please add the information. (3) In page 9 line 6 from bottom, the data are divided into three categories of HL: inadequate, problematic, and sufficiently functional or communicative and critical. Could the authors define and explain the reference cut-off values for the total scores of Swedish FHL scale and C & C HL scale? (4) In page 11 line 2–5, 20 persons who participated in the qualitative study will be included by a purposeful sampling and will be selected to ensure maximum variation regarding age and gender. How will the authors identify the maximum variation in the age and gender? I want to know what is the maximum variation is acceptable (what will be deviation allowed). (5) In Table 1, given several measure items are duplicated. Please modify according to my suggestion (see attached document). Also, why participants are not evaluated the comorbidities in the period of 30 days, 1 year and 2 years after surgery because patient's comorbidities will change with the time? The authors need to explain and clarify. 3. In the Discussion section, (1) In page 15 line 6, 'Nor' have research questions such as ours been reported before. This made me confused and pleases correct. (2) In page 15 line 1 from bottom, '……., a cost-effective care can be provided.' The authors need to show that the interpretation of the results in terms of the cost-effective care. The authors need to clarify in the limitation of the study because other unmeasured factors, such as the patient's period of psychostimulant use, drug addiction severity, and other comorbidities may also influence the risk of fatal stroke in adults aged 15–44 years (page 12, line 5–6 from bottom). In addition, the results may generalize only to Australia. A highly diverse development of the national drug policy and strategy, so these potential factors can make the results less generalizable to other countries. Please state in the text. (3) Practical implications of results needs to be explained more detail based on the findings of this study. 4. The 'citation formatting' of the References (Ref no. 13, 15, 20, 31, 42, 43, 44, 55) is incomplete. Most importantly, the authors should carefully revise the reference formatting based on the Authors of BMJ Open. And Ref no. 42 and 58 are cited inconsistent. Most importantly, the authors should carefully revise the reference formatting based on the Authors of BMJ Open.

	Minor: In page 5, line 4, '……limited HL uses more 'in-' and outpatient care." Please change the 'in-' to 'inpatient'.

VERSION 1 – AUTHOR RESPONSE

Reviewer 1	
With that intention, the author(s) of the current manuscript being reviewed failed to provide sufficient information in the discussion section to support the study need and possible implications to practice, education, policy and future research.	The discussion has been clarified. If the patients can strengthen their self-efficacy, they may feel empowered to handle their situation Also, if information provided is appropriate according to their level of health literacy, patients may be able to manage their postoperative recovery. Furthermore, perhaps readmissions due to non-specific conditions can to some extent be avoided, that is, a cost-effective care can be provided.
Page2, line 25-32: Long sentence that loses meaning to the reader and is confusing. Please rework. Remover "There is, therefore, a…" and replace with "The need to investigate…" This phrase deletion provides a clearer message.	Thank you for the suggestion to rephrase this sentence. The sentence is rephrased The need to investigate how a person's self-efficacy and health literacy skills affect recovery as well as health-related quality of life after bariatric surgery is important. It can involve the person in the care, improve shared decision-making, and perhaps decrease complications and readmissions.
Page 2, line 40: correct to read "...Sweden; 20 patients will be included…" Add phase or component after "qualitative study" as this demonstrates more of the mixed-methods part of this study (via qualitative phase and quantitative phase) rather than making it seem there were 2 studies being completed. Be sure reference to the study phases are expressed throughout the paper in the same manner.	The sentence is rephrased This is a prospective, longitudinal mixed-methods study with the intent of including 700 patients from three bariatric centers in Sweden (phase 1); 20 patients will be included in a qualitative study (phase 2).
Page 2, line 53: remove "the" before patients.	Amended
Encourage authors to identify the specific questionnaires' names being used in the introduction.	The instruments have been clarified. Before surgery patients will answer a questionnaire including 20 items. Valid and reliable instruments will be used to investigate general self-efficacy (10 items) and functional and communicative and critical health literacy (10 items).
Page 4, line 43: Regarding "Younger age and female sex…" this finding is not surprising as	An increased risk for readmission and poorer postoperative recovery have been reported in other

70-80% of all patients seeking bariatric surgery are female. I would discuss that thought in your conclusion and how you may sample to ID possible gender differences.	fields of surgery. As pointed out by the reviewer, more women than men undergo bariatric surgery. It would seem reasonable to assume that follow-up programs and perioperative information would be adapted to the needs of the specific group of patients operated. For this reason, the association may be somewhat different for bariatric surgical patients. In the quantitative analyses, adjusted analyses including age, and sex will be performed.
Page 5, line 29 and line 56: add comma after "To our knowledge,"	Amended.
Page 6, line 25: Is the third hypothesis accurate enough? Is Health literacy the sole factor to have an impact on hospital readmission? Would it read better if you add to the statement, "… and subsequently weight loss"	We believe that the ability to fully understand received information can have an impact om readmission. If the person has difficulties to understand written information about self-care, it could possibly affect readmission to hospital.
Page 7, lines 17-19: can you identify these sites in the online publication? Is the study still in progress?	Thank you for this comment! The study is indeed in progress. We have revised this information within the manuscript.
Page 7, line 41: comment- how is EBMIL different than the excess weight loss (EWL) commonly used post-bariatric surgery?	Weight-loss can be measured in different ways. Percentage Excess-BMI loss (%EBMIL) is one of these. EBMIL tend to overestimate treatment effects in patients with relatively low BMI. However, the majority of patients included in the present study will have a BMI of 35-50, thus representing a lower mean preoperative BMI compared to other populations of bariatric surgical patients, such as in the US.
Page 7: Details about a priori sampling was calculated in the study sample was not fully expressed.	The assumptions of the Power calculations was based on the average weight-loss in Sweden. Furthermore, we considered a reduction of EBMIL to 75% to be a clinical relevant difference. We have tried to further clarify this within the revised version of the manuscript.
Page 7, line 52: First sentence is not structurally sound. Please rephrase. Consider the following, "During their preoperative consultation the surgeons will verbally provide information about the study."	Amended
Page 8, lines 42-47: Confusing sentence " The GSE has been …." Unclear what versions were all tested.	This has been clarified in the manuscript. The instrument consists of 10 items rated on a four-point Likert scale (ranging from not at all true to exactly true) and it has been translated into different languages. The instrument has been psychometrically evaluated with samples from 25 countries.

Page 9, line 13-14: Was tool tested on same population? What were the Psychometric testing results?	It was tested on patients with type two diabetes. Internal consistency was adequately high for the three scales (Cronbach alpha for the three scales were as follows; FHL 0.84, communicative HL 0.77 and critical HL 0.65 (Ishikawa et al., 2008). The short version of C&C HL was tested on general population with item content and mean scores only (Ishikawa et al., 2010).
Page 9, lines 16-29: The three factors discussed here—Functional, communicative and critical literacy—are these measured with the short form or original tool or both? Please clarify.	FHL and C& C FL has been translated to Swedish and tested psychometrically in earlier research. These two scales are used in this research. FHL is measured with five items and C&CHL is measured with five items. In the manuscript it is written The Swedish FHL scale, has five items, answered on a five-point Likert scale (never, seldom, sometimes, often, and always). The Swedish C & C HL scale has five items (i.e., translated from the short version of C and C HL), measured on a five-point Likert scale
Page 9, lines 36-41: odd phrasing. Rework sentence.	The sentence has been rephrased The data are divided into three categories of HL: inadequate, problematic, and sufficiently functional or communicative and critical when analyzing results.
Page 9, lines 44-49: OK, what psychometric testing will be achieved in your study. Reference to Table 2 is needed. Also consider prioritizing the order of the psychometric evaluation plan in Table 2 (on page 13).	The psychometric testing that are planned are presented in the section statistical analysis and the testing will be guided by COSMIN manual. Table 2 has been clarified. The psychometric analysis will be guided by the Consensus-Based Standards for the Selection of Health Measurement Instruments (COSMIN) manual (Table 2).
Page 10, line 3: RAND needs to be spelled out and then identified by abbreviation.	The abbreviation has now been spelled out in the manuscript.
Page 10, lines 20-31: In the section called Obesity-related problem scale more information is needed. Provide more information on who and how this tool was developed and tested. Is this test appropriate for use in a surgical population? What is the intent of using this tool in your study—will it help measure self-efficiacy?	The Obesity –related problem scale is included in the Scandinavian Obesity Surgery Registry. The obesity-problem scale is generally considered to be a more valid estimation of health-related quality-of-life in an obese population compared to other available estimates. It is included in the analysis though it will describe the group's well-being and it may also correlate to self-efficacy. The reference provided (ref 56)

	describes the development and validation of the OP-scale. Clarified in the manuscript Psychometric testing showed a strong construct validity, high internal consistency with a Cronbach alpha above 0.90 and exploratory factor analysis showed unidimensionality.
Page 10, lines 44-51: Demographics being collected should be identified in more detail. Is there a demographics form that will be used? Is this information extracted from SOReg? If so, please reference Table 1.	The demographic variables are all presented in table 1 and these variables are documented in the registry (SOReg). In the paper based form including GSE and FHL and C &CHL is also estimated health economy collected as it is not a variable in SOReg.
Page 11, lines 3-4: sentence as written is oddly worded. Rephrase, "Twenty persons who participated in the main study will be included in a qualitative phase using an inductive approach."	Amended
Page 11, line 8: remove "the" that preceeds surgery. Also identify "surgery" as bariatric surgery here and throughout your manuscript.	The sentence has been rephrased and bariatric has been inserted throughout the manuscript.
Page 11, line 13: Mention of a semi-structured interview guide is given. Can this be included as a Figure or Table in your manuscript?	We thank the reviewer for this suggestion however we prefer to write the questions in the section that describes the qualitative study.
Page 11, line 15: Delete "could you" and start sentence with Describe.	Amended
Page 11, line 17: remove "the" before surgery. Change to bariatric surgery.	Amended
Page 11, Table 1: Some areas on this table can be combined…For example, BMI and weight variables can be inclusive of all time periods. It is redundant to have "weight at surgery and weight" listed.	Thank you for pointing out this error, the table has been modified
Page 12, line 39: Delete "to analyze" and start sentence with Demographics. Fix grammar within this sentence to improve reading fluidity.	The sentence has been rephrased. Demographic variables, will be analyzed with descriptive statistics with number, percentage, mean, and standard deviation or median (range), as appropriate.
Page 12, lines 42-onward: It would be nice to see the expected statistical test connected to the intended study instrument/tool. For	Thank you for this suggestion however we think this type of presentation will decrease readability

example, GSE will potentially be analyzed using….	though test will be repeated when presenting each instrument solely.
Page 13, line 9: Start sentence with Psychometric analysis will be… (Beware excess use of "the")	Thank you for pointing this out. The removal of "the" has been amended.
Page 13, line 49: Interviews will be recorded with what device? Who will be conducting the interviews?	It has been clarified in the manuscript Interviews will be conducted by the research team. All interviews will be audio recorded, using Philips, DVT6010.
Page 14, line 22: Ethics perspective is quite short and not comprehensive of patient protection. Expand to include information that will demonstrate privacy, confidentiality and mechanism to seek help if harmed.	The study will be conducted in accordance with the ethical standards of the 1964 Helsinki declaration and its later amendments. In accordance with these standards, the autonomy of each patient must be fully respected.
Page 14, lines 26-28: Delete first sentence "The study will follow…."	In the authors opinion, the Helsinki declaration must be followed when conducting research involving humans. Most of the potential ethical issues that may arise in a study such as the present are addressed within this declaration and it is our opinion that this sentence should be sufficient. We would therefor like to keep this sentence within the manuscript although slightly revised.
Page 14, line31: delete "received" and insert "will"	Amended
RE recruitment: when does inclusion criteria check occur?	During the preoperative consultation
RE qualitative phase procedure: how are final themes extracted from the data checked for creditability? Consider sharing Lincoln and Guba's validity checks throughout the process.	The procedure has been clarified in the manuscript None of the researchers conducting the interviews will be involved in the care of the included participants. Thematic analysis, described by Braun & Clarke, will be used to provide in-depth analyses of patients' experience of postoperative recovery after bariatric surgery. To assure trustworthiness and rigor, analyses will adhere to the quality criteria outlined by Lincoln and Guba (credibility, confirmability, dependability, transferability). All interviews will be recorded and transcribed verbatim. Analyses will start with the researchers listening to the recorded interviews and then reading through the transcribed interviews to familiarize themselves with the data. During the analysis the researchers pre-understanding will be taken under consideration. After reading through the interviews, the coding process will be

	conducted, and the codes will be searched for patterns. Codes will be gathered together in subthemes and themes that respond to the research question.
RE GSE instruments: specify version being used and actual or real psychometric properties.	This has been clarified in the manuscript. The instrument consists of 10 items rated on a four-point Likert scale (ranging from not at all true to exactly true) and it has been translated into different languages. The instrument has been psychometrically evaluated with samples from 25 countries
Throughout your manuscript pay particular attention to sentence structure and grammar.	Amended
Regarding ethical concerns. Please expand discussion to provide information on how patient identify will be maintained through copies of data (surveys) and interviews. Who will have access? Where will information be kept when not used by researcher or research team?	Data will only be available for the researchers and a data management plan will be used. Data will be kept on a location only accessible to the study group. This is in accordance with the current legislation in the EU and was specified and approved by the Regional Ethics Committee. It is the authors opinion that the information provided in the manuscript should be sufficient to the readers.
Page 14, line 40: rephrase to, “This open-access article is distributed…”	This phrase was suggested during the submission-process. If editor wants to delete this sentence it is fine for the authors.
Page 15, line 20: This statement “Nor have research questions such as ours been reported before” Is a sentence fragment—please fix.	This sentence has been rephrased To our knowledge neither GSE nor HL have been investigated in patients undergoing bariatric surgery, and research questions such as ours has not been reported before.
Page 15, line 37-49: rework to read as follows, “If patients can strengthen their self-efficiacy, they may feel empowered to handle their situation. Also if information provided is appropriate according to their lebel of health literacy,”	The sentence has been rephrased as suggested
Page 15, line 42-44: “able to handle” and “to some extent be avoided” is jargon. Please rework.	The sentence has been rephrased patients may be able to manage their postoperative recovery
Reviewer: 2	
I am not an expert is power calculation but I would ask the authors to double check the expected weight loss figures. The high % Excess BMI Loss expected presumably relates to the relatively low initial BMI of	Weight-loss can be measured in different ways. Percentage Excess-BMI loss (%EBMIL) is one of these. We fully agree with the reviewer that %EBMIL tend to overestimate treatment effects in patients with relatively low BMI. However, the

patients operated in Sweden and is the 1 or 2 year weight expectation. Have the authors taken into account expected weight regain after this time e.g. at 3-4 years after surgery and how would this affect sample size and generalisability of the results? Have the authors taken into account possible poorer weight loss in males and diabetics?	majority of patients included in the present study will have a BMI of 35-50, thus representing a lower mean preoperative BMI compared to other populations of bariatric surgical patients, such as in the US. The study is a multicenter trial including patients from three centers for bariatric surgery in Sweden. These three centers does well represent the general population of bariatric surgical patients in Scandinavia (and northern Europe). The Power calculation was based on the assumption of a clinical relevant difference in weight-loss compared to the average weight-loss in Sweden over two years after surgery. Although we fully agree with the reviewer that longer follow-up time is of interest we know from experience that it is hard to retain high follow-up rates after 2 years. We did not consider other factors potentially influencing postoperative weight-loss since the main question was whether or not health literacy and self efficacy influence postoperative outcome after bariatric surgery. However, we fully agree with the reviewer that these outcomes should be analyzed and presented as adjusted risk measures (adjusted for known or presumed factors such as age, sex, BMI and specific comorbidities) as well. This has been clarified within the revised version of the manuscript. For the analyses on weight-loss and HRQoL, multivariable regression analyses including other factors potentially influencing postoperative weight-loss will be performed.
The study should gather the information on patients entering the study vs all those approached to ensure data are representative of the whole population.	We fully agree. All patients considered for inclusion are registered. Due to the current legislation on collection of data (GDPR) we are not allowed to follow patients who do not agree to participate in the trial. However, we will be able to record the number of patients not agreeing to participate at each center. We will also be able to compare the study population to all patients operated at the study centers during the study period. The manuscript has been revised in accordance with the comment from the reviewer. As a sensitivity analysis, patients included in the study will be compared in terms of baseline characteristics with those not included in order to identify potential risk for selection bias.
The choice of Clavien-Dindo of 3b and above should be explained, and an explanation of	We fully agree with the reviewer that all definitions should be very clearly presented. This has been

what Clavien-Dindo is as well should be included if the authors think appropriate. Will they include diagnostic laparoscopy?	clarified within the revised manuscript. Although a definition of serious complication as being a complication requiring intervention under general anesthesia, resulting in organ failure or death of the patient, can be viewed as quite clear, one critique that has been raised concerns the definition of the complication itself. However, a diagnostic laparoscopy is always performed as a response to relevant symptoms (severe pain, or tachycardia without other explanation in the early postoperative period). In our opinion, a diagnostic laparoscopy with negative findings should still be considered a serious complication. This may of course over estimate complication rates. However, by reporting all serious complications it is our opinion that secondary analyzes can be made using other definitions of a serious complication. Postoperative complications will be classified in accordance with the Clavien-Dindo scale [45] with complications graded as 3b or more (i.e. a complication requiring intervention under general anesthesia, resulting in single- or multiorgan failure, or death) being considered to be serious complications. Diagnostic laparoscopy with negative finding in the early postoperative phase (during Day 0-30) will be considered a serious complication.
Which is the baseline weight? That on entry to the weight loss programme or that on the day of surgery? The authors should consider both if there is a preoperative weight loss programme in place.	We consider base-line weight as weight before preoperative weight-loss. The main reason for this is that we consider the preoperative weight-loss as being part of the treatment plan. We do know that patients loosing more weight before surgery (at least up to 10% of their total weight) have better postoperative results (in terms of risk for postoperative complications and postoperative weight-loss). However, we do agree with the reviewer that both weights should be presented and incorporated in the study. A pre-operative weight-loss regimen of 2-4 weeks on a very-low carbohydrate diet is standard at all centers within the study. Weight-loss will be reported as changes in BMI, %EBMIL, and percentage total weight-loss (%TWL). Furthermore, a good weight-loss result will be defined as EBMIL >50%. The weight before preoperative weight-reduction will be considered as baseline weight.
Please explain why it was chosen not to involve patients in study design.	This can be seen as a limitation of our design however, this is a hypothesis generating study

	which can generate new research questions. If an intervention is performed in the future, patients will be included in the design of the study.
Reviewer: 3	
In the Introduction section, (1) In page 5 line 7, '……, depending on fluctuations in one's own personal belief in personal efficacy.' This sentence made me confused. Could the authors please explain a bit?	A person's self-efficacy can fluctuate depending on beliefs in one's own efficacy beliefs and it can vary in level, strengths. The outcomes that comes from an action can take a form of positive or negative outcomes.
In the Methods and Analysis section, (1) The authors must remember that participants have the right to refuse or withdraw consent at any time for any reason. Please explain how to adapt to the circumstances and state in the text.	The study will be conducted in accordance with the ethical standards of the 1964 Helsinki declaration and its later amendments. In accordance with these standards, the autonomy of each patient must be fully respected. A potential problem if a significant subgroup of patients refuse to participate may be that of a selection bias. This can only be handled by close monitoring of the study group. We have planned to perform a sensitivity analysis comparing patients participating to all other patients operated at the participating centers during the same period of time. This has been specified within the revised version of the manuscript. As a sensitivity analysis, patients included in the study will be compared in terms of baseline characteristics with those not included in order to identify potential risk for selection bias.
Do participants who reported low self-efficacy will be judged by a clinician or psychological expert? Please add the information.	Patients with known history of psychiatric disorders will always be reviewed by the physician (psychiatrist or general physician) or psychologist treating the relevant condition prior to acceptance for bariatric surgery. We do not have the routine of sending patients with low self-efficacy for evaluation of a psychologist before surgery. Based on the low evidence to support such examination before surgery this will not be the routine during this study as well. However, we do hope that within the frame of this study we will be able to identify groups of patients in need of preoperative intervention. However, the intervention itself must be the focus of future intervention studies.
In page 9 line 6 from bottom, the data are divided into three categories of HL: inadequate, problematic, and sufficiently functional or communicative and critical. Could the authors define and explain the	Each value is coded according to an instructor's manual. ≥1000 is inadequate FHL or C & C HL >100 but <1000 is problematic FHL or C & C HL <100 is sufficiently FHL or C & C HL

reference cut-off values for the total scores of Swedish FHL scale and C & C HL scale?	
In page 11 line 2–5, 20 persons who participated in the qualitative study will be included by a purposeful sampling and will be selected to ensure maximum variation regarding age and gender. How will the authors identify the maximum variation in the age and gender? I want to know what is the maximum variation is acceptable (what will be deviation allowed).	The sampling will be guided by the quantitative data collection (since this is a mixed method study with an embedded design), therefore it is not possible to decide the deviation before self-efficacy, age and gender have been analyzed. Inclusion criteria will be those with low self-efficacy. Maximum variation will be conducted meaning that gender, age differences and patients' from all centers will be included. We have clarified in the manuscript as well as added a reference regarding maximum variation: Data will be collected 1 year after bariatric surgery. A purposeful sampling will be conducted. Participants who reported low self-efficacy will be included and will be selected to represent maximum variation regarding center, age and gender
In Table 1, given several measure items are duplicated. Please modify according to my suggestion (see attached document). Also, why participants are not evaluated the comorbidities in the period of 30 days, 1 year and 2 years after surgery because patient's comorbidities will change with the time? The authors need to explain and clarify.	Thank you for highlight this error, we have modified the table. Information on comorbidities over time will be extracted for the reasons presented by the reviewer. However, the study was not designed to address differences in effect on comorbidities (such as resolution of diabetes etc) and is likely to be underpowered for such analyses.
In the Discussion section, (1) In page 15 line 6, 'Nor' have research questions such as ours been reported before. This made me confused and pleases correct.	This sentence has been rephrased To our knowledge neither GSE nor HL have been investigated in patients undergoing bariatric surgery, and research questions such as ours has not been reported before.
In page 15 line 1 from bottom, '……., a cost-effective care can be provided.' The authors need to show that the interpretation of the results in terms of the cost-effective care.	Cost- effectiveness is not the focus in this study. However, if readmissions can be avoided when appropriate information is given according to literacy level, it has a possibility to be cost-effective.
The authors need to clarify in the limitation of the study because other unmeasured factors, such as the patient's period of psychostimulant use, drug addiction severity, and other comorbidities may also influence the risk of fatal stroke in adults aged 15–44 years (page 12, line 5–6 from bottom).	Substance abuse may be linked to important socioeconomic aspects. It is likely that patients with previous substance abuse will be included within the study. However, for all patients with previous substance abuse, 2 years documented abstinence and approval from a psychiatrist (or other physician responsible for the treatment of the dependency disorder) are required. However, we acknowledge that substance abuse is a problem after bariatric surgery and have listed this as a limitation of the study design.

In addition, the results may generalize only to Australia. A highly diverse development of the national drug policy and strategy, so these potential factors can make the results less generalizable to other countries. Please state in the text.	In our bullet points we state that the study is performed in Sweden
Practical implications of results needs to be explained more detail based on the findings of this study.	It is difficult to predict practical implication in this stage. We have described in the discussion that a future study may investigate how to strengthen a person's self-efficacy or to use information appropriate for a person's literacy level. However, this will be based on the result from this present study.
The 'citation formatting' of the References (Ref no. 13, 15, 20, 31, 42, 43, 44, 55) is incomplete. Most importantly, the authors should carefully revise the reference formatting based on the Authors of BMJ Open. And Ref no. 42 and 58 are cited inconsistent. Most importantly, the authors should carefully revise the reference formatting based on the Authors of BMJ Open.	Amended
In page 5, line 4, '……limited HL uses more 'in-' and outpatient care." Please change the 'in-' to 'inpatient'.	Amended

VERSION 2 – REVIEW

REVIEWER	Karen D. Groller, PhD, RN-BC, CMSRN Moravian College, Bethlehem, PA, USA
REVIEW RETURNED	11-Jan-2019

GENERAL COMMENTS	Thank you for the opportunity to review your revised manuscript. This research is needed. I believe your recent revisions has created a stronger paper but still work needs to be done to prepare for publication. Method and analysis section is missing some details. Discussion is too short and does not connect study aims to practice significance/implications. Limitation section should be expanded upon and provide rationale as how these limitations were balanced or minimized. See attached pdf with my revisions and comments. The reviewer provided a marked copy with additional comments. Please contact the publisher for full details.

REVIEWER	Richard Welbourn Dept. UGI and Bariatric Surgery Musgrove Park Hospital Taunton TA1 4DA UK
REVIEW RETURNED	27-Dec-2018

GENERAL COMMENTS	The authors appear to have addressed the 3 reviewers' comments appropriately, certainly mine, on their paper on self-efficacy and health literacy in Swedish bariatric surgery patients. I am happy with the revised manuscript. The results will be very informative in due course.

REVIEWER	Chun-Che Huang Taichung Veterans General Hospital/ Taiwan
REVIEW RETURNED	07-Jan-2019

GENERAL COMMENTS	Thank you for the authors' efforts. I have no more questions about the revision.

VERSION 2 – AUTHOR RESPONSE

Reviewer 1	
Method and analysis section is missing some details.	We have tried to clarify these sections accordingly.
I believe you need an individual hypothesis on your HRQoL as this is the third concept being studied	The third hypothesis is as follows, There is an association between HRQoL and HL and GSE
Discussion is too short and does not connect study aims to practice significance/implications.	As this is a study protocol we have no results yet, although we have tried to discuss the aim of the study in relation to Swedish legislations, clinical practice and future implications/support.
Limitation section should be expanded upon and provide rationale as how these limitations were balanced or minimized.	This section has been expanded
GK1: Is this expectation documented somewhere?	We are not sure if we understand your question. Explicitly it is not documented in a care plan however, research focusing on recovery after day surgery shows that patients feel lonely and abandoned after discharge. Since recovery after surgery is mostly managed by patients at home, the health care providers expect the patient to get in contact if there is something wrong with the recovery.
GK2: Are you focusing on particular procedure type? i.e.-sleeve gastrectomy, RNY, band? If so	We are focusing on primary bariatric surgical procedures which primarily consists of sleeve gastrectomy or Roux-en-Y gastric bypass

state this.	(GBP). Therefore the study will focus only on primary GBP and sleeve gastrectomy. This has been clarified in the methods section of the revised version of the manuscript
GK 3: Share what these are. Consider sharing as table/appendix	The instruments are described in detail in the method section.
GK 4: I recommend the way you frame your question in your abstract, this section and rest of paper remains consistant. Currently they are not and can be interpreted differently,	We are sorry, but we do not understand this comment. There are no questions in the abstract.
GK 5: Remove jargon. Consider "This research addresses a person-center approach…"	Amended
GK 6 : The revised draft contradicted itself making results generalizable but limited to Swedish population. I attempted to fix for you here.	Thank you for your suggestion. The sentences has been clarified.
GK 7: Cite evidence	Amended
GK 8: This statement is confusing….so 8.7% experience complications within 30 days. Is the 14% of those 8.7% visiting EDs, 6-8% of the readmission rates part of the original 8.7%? Where is the other percentages? Clarify.	The sentence has been clarified
GK 9: Is this due to 80% of those undergoing bariatric surgery are female?	Yes, women are prone to experience a poor recovery as well as younger age is an independent factor associating with poor recovery.
GK 10: What kind of association? Direct/indirect, positive vs. negative?	Positive
GK 11: Authors briefly mention GSE will be measured using a "valid" instrument. HL and HRQoL measurement instruments were not discussed/shared and should be.	The instruments are described in detail in the method section.
GK 12: What variables will be measured to evaluate this? Just change in bodyweight, %FFM, etc???	Weight-changes will be measured as changes in BMI, %EBMIL and %TWL in accordance with the ASMBS recommendations. This has been clarified under "Definitions"
GK 13: So you plan to do psychometric testing on GSE and HL instruments in patients with obesity?	Yes, see table 2.
GK 14: Ok what was used to determine this? G*Power?	We agree with the reviewer that the assumptions of the Power calculations should be transparent to the reader. This has been clarified in the revised version of the manuscript

	in accordance with the comment from the reviewer.
GK 15: Seems this is missing some other key terms/ variables i.e.-HRQoL score, GSE score, coding of demographics	Instructors manual will be used for each instrument. For example for health literacy each value is coded according to an instructor's manual. ≥1000 is inadequate FHL or C & C HL >100 but <1000 is problematic FHL or C & C HL <100 is sufficiently FHL or C & C HL. We agree with the reviewer that the analysis are briefly described here. However, this is the protocol describing this study. We do not think that it is relevant and of interest for the readers to describe coding process for each variable in this manuscript. All analyses will be carefully described in future publications.
GK 16: need brief overview in introduction to clarify these tools will be used.	In the introduction we describe the concept of self-efficacy and health literacy and if describing the tools in the introduction there is a risk for repeating this information.
GK 17: How will participant's readability be determined? Typically health literacy means that patient information will be evaluate for readability	There will be no test assessing readability of patient information before inclusion. Since this has not been performed before we include patients consequently and the result will show the prevalence of patients with limited health literacy skills. We agree with the reviewer that patient information should be checked for readability before handed out to patients. Unfortunately, this is not clinical routine.
GK 18: Citation needed?	The whole section is cited from ref. 58.
GK 19: Hyphenations should be used	Amended
GK 20: hyphenate	Amended
GK 21: nice table. This helps answer my previous question.	Thank you
GK 22: What about member checking with some of the 20 participants after themes and subthemes are generated.	The analysis will follow the steps outlined by Braun and Clarke. Member checking is not included in Braun and Clarkes guide for thematic analysis
GK 23: This concept should be further explained in this discussion. By doing this readers will understand better the current trend in Swedish Healthcare and may be able to transfer concept to their own healthcare situation.	This concept has been further explained according to Swedish legislations.
GK 24: This section is extremely short and should contain more discussion. You need to demonstrate significance between GSE, HL and HRQoL and how studying	We agree with the reviewer, however, as this is a study protocol we have no results yet, although we have tried to discuss the aim of the

these relate back to your research aims.	study in relation to Swedish legislations, clinical practice and future implications/support.
GK 25: What about self-reported Questionnaires? Truthfulness? How will you eliminate interviewer's bias for qualitative arm? This section should consider the limitations for all study phases and address in that manner. Also beyond addressing limitations, authors should state how they are trying to balance or minimize these limitations	Self-reported questionnaires could be used however there are no opportunities to ask any supplementary questions if the answer is unclear or need to be further explicated. We therefore decided to perform interviews. The limitation section has been expanded.
GK 26: Should share why this will occur	In our opinion it should be well known to the readers of the article that more women than men undergo bariatric surgery. It is likely that this discrepancy will remain during the inclusion period of the study. We have rephrased this section as a response to the reviewer's comments.
Reviewer 2	Thank you for your feedback
Reviewer 3	Thank you for your feedback

VERSION 3 - REVIEW

REVIEWER	Karen D. Groller Moravian College, USA
REVIEW RETURNED	27-Feb-2019

GENERAL COMMENTS	See attached files. Introduction is still a bit unorganized (can refine to make significance and study intensions known earlier on), but other sections have improved. Thanks for the opportunity to review your work. Good luck on the rest of the study. The reviewer provided a marked copy with additional comments. Please contact the publisher for full details.

VERSION 3 – AUTHOR RESPONSE

Please correct "och" in line 54, page 5.	Amended
Page 9, line 22: Please edit the following sentence to improve the clarity: "The	The sentence has been rephrased

Scandinavian Obesity Surgery Registry (SOReg) is a quality and research register.”	
Please ensure that all abbreviations have been defined on first mention; eg, have the terms in the following sentence in the methods been previously defined? “Weight-loss will be reported as changes in BMI, %EBMIL”	EBMIL is defined in the introduction. BMI has been defined in the method section.
Please make the changes to page 10 (Instruments section) as requested by the reviewer (see attachment).	The reviewer wants clarification if GSE is an instrument or a scale. We understand the confusion about instrument or scale since the words are used interchangeably. The method section now uses the word scale. The reviewer lacks a reference, however the sentence refers to reference 49 and the second section refers to reference 50. The reviewer wonder if the short version of C & CHL was tested. The researchers performed item content and mean scores. This short version has been translated and tested in a Swedish context, however more psychometric testing is warranted.
- Please also make the suggested changes to table 1.	Amended